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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,623	03/04/2002	Ulf Eriksson	1064/44833C2	8185
23911	7590	10/31/2005	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,623

Applicant(s)

ERIKSSON ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14,17 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14,17 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/09/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claim 15-16, 18-22 and 24-29 are canceled. The amendment of claims 1, 4, 5-7, 14 and 23 has been made of record.

Claims 1-14, 17 and 23 are pending and are examined on the merits to the extent that they read on the elected polynucleotide sequence encoding the polypeptide of amino acid sequence of SEQ ID NO: 6.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Objections/Rejection withdrawn

Applicant's argument for information disclosure statement (IDS) filed on 09/09/2004 is persuasive and the references Miyama and Voet are initialed.

The objection to claims 1, 4, 5-7 and 23 has been withdrawn in view of Applicants' amendment to claims.

The rejection of claims 10-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement with respect to the recitation of a host cell is withdrawn in view of Applicant's arguments, see Remarks, filed on 8/5/2005.

The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's claim amendment.

Claim Rejections – maintained

Claim Rejections - 35 USC § 112-written description

The rejection of claims 1-14, 17 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of records in the Office Action mailed on 2/8/2005.

Claims are drawn to an isolated polynucleotide having at least 85%, 90 % or 95% identity with the nucleic acid sequence of SEQ ID NO:5 that encodes polypeptide of amino acid SEQ ID NO: 6 and a polynucleotide which hybridizes under stringent condition to one of claimed sequences.

Applicants argue that the possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was ready of patenting by the disclosure. They argue that the specification teaches that PDGF-D polypeptide is a growth factor and they disclose the nucleic acid sequence of PDGF-D (partial human clone) as the SEQ ID NO:5 that encodes hPDGF-D of SEQ ID NO: 6.

Applicants' arguments have been fully considered but are not found to be persuasive. Claims are drawn to an isolated nucleic acid comprising a polynucleotide encoding a PDGF-D activity and having a sequence identity of at least 85%, 90 % or 95% to nucleotides 1 to 966 of SEQ ID NO: 5 or a polynucleotide which hybridizes under stringent condition with any of the above disclosed sequences. The specification

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has disclosed only a nucleic acid sequence of SEQ ID NO: 5 in the genus of claim nucleic acid sequences. To provide undisclosed possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics for the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the chemical product, or any combination thereof. There is not even identification of any particular portion of the structure that must be conserved to have PDGF-D activity. Further, the recited activity is not specific because specification discloses that the PDGF-D activity is defined as "the ability to stimulate or enhance, or both of proliferation, differentiation, growth and motility of a cell expressing a PDGF-D receptor". These biological activities are very broad. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The specification does sequences having mutation, deletion or substitution to the SEQ ID NO: 5 having a disclosed PDGF-D activity. As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolating it. The compound itself is required.

Claim Rejections - 35 USC § 112-enablement

The rejection of claims 1-14, 17, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for the reasons of

record in the previous office action.

The invention is drawn to (i) polynucleotide encoding a polypeptide having the amino acid sequence set forth in SEQ ID NO: 6 or (ii) a polynucleotide having nucleic acid sequence at least 85%, 90 % or 95% identical to the nucleic acid sequence given in SEQ ID NO: 5 or (iii) to a polynucleotide which hybridizes under stringent condition to one of claimed sequences.

Applicants argue that the specification discloses nucleic acid sequence of the SEQ ID NO: 5 that encodes the polypeptide PDGF-D of SEQ ID NO: 6. One skill of the art would understand degenerative nature of the genetic code to make a protein having PDGF-D activity.

Applicants' arguments have been fully considered but are not found to be persuasive. The specification does not disclose any conserved sequence that is required for a PDGF-D activity which is self very broadly defined. One of skill in the art would know how to make a mutation or deletion but not knowing what sequences are essential for the disclosed activity, one would not be able to accomplish innumerable possibilities required to full scope of the claimed invention. This is merely an invitation to the artisan to use the invention as a starting point for further experimentation and undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The rejection of claims 1-14, 17, and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention is maintained for the reasons of record in the previous Office Action mailed on 2/8/2005.

Regarding claim 1, the phrase "stringent conditions" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. The limitation "stringent conditions" is conditional and the defining conditions are not recited in the claim or the specification. See MPEP § 2173.05(d).

Applicants argue that one of ordinary skill in the art would clearly understand the term "stringent condition" because hybridization techniques are well known in the art at the time of the invention.

Applicants' arguments have been fully considered but are not found to be persuasive. Although it is well known in the art how to perform a hybridization when a condition is provided, it is not well known in the art what stringent condition one of skill in the art would use for identifying a nucleic acid with at least 85%, 90 % or 95% identical to the nucleic acid sequence given in SEQ ID NO: 5.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra, Ph.D.
Art Unit 1646
19 October 2005


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER